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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/507,221

04/15/2005

Mark M. Goodman

51-02

2692

23713

7590

07/18/2008

GREENLEE WINNER AND SULLIVAN P C

4875 PEARL EAST CIRCLE

SUITE 200

BOULDER, CO 80301

EXAMINER

ZUCKER, PAUL A

ART UNIT

PAPER NUMBER

1621

MAIL DATE

DELIVERY MODE

07/18/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/507,221

Applicant(s)

GOODMAN ET AL.

Examiner

Paul A. Zucker

Art Unit

1621

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 4/30/2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 and 45-52 is/are pending in the application.
- 4a) Of the above claim(s) 46 and 48-52 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-27, 45 and 47 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-27, 45 and 47 are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 September 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 8/8/07, 4/21/05
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I, and further election of the compound 5b on page 30 of the specification, in the reply filed on 30 April 2008 is acknowledged. The traversal is on the ground(s) that no reasoning was given for the differences between Groups I and II. The Examiner disagrees with Applicants' position since a clear reason for the lack of a special technical feature, namely the lack of a common core, was clearly set forth. This lack of a special technical feature is undisputed by Applicants. Upon reconsideration, however, the Examiner has decided to withdraw the restriction of the method claim from the compound claims. Based on Applicants' election, the claims 1-27, 45 and 47 are sufficiently structurally related to Applicants' election, or dependent upon compound claims that are, to be grouped together. Claims 46 and 48-52, having a radically different structure including the Z group, not present in the prior group of claims, are held withdrawn from consideration as being drawn to a non-elected invention.

Specification

2. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.
3. The abstract of the disclosure is objected to because it is too long. The abstract should consist of a single paragraph of 150 words or less. Correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 1-27, 45 and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goodman et al (US 5,808,146 09-1998) when considered with Christensen et al (The Journal of Biological Chemistry, 1965, 240(9), page 3609-3616).

Instantly claimed are halogen radiolabeled amino acid analogs as set forth in the claims and a method for their use in a method for *in situ* tumor imaging by positron emission tomography.

Goodman teaches (Column 33, line 1-column 34, line 64, claims 1-27) a genus and sub-genii of radiolabeled compounds closely related in structure to those instantly claimed. Goodman further teaches (Column 3, line 25- column 4, line 23) a method for using these compounds for *in situ* tumor imaging by positron emission tomography (PET).

The difference between the compounds and methods of Goodman and those instantly claimed is that Goodman's compounds have a primary amino group on the amino acid a carbon while those instantly claimed bear an additional alkyl group. For example the instantly elected specie, compound 5b, corresponds to the compound of Goodman in which $R_1=X$; $X = {}^{18}\text{F}$; $R_2 = \text{H}$; $z=2$, $y=1$, with the only difference being that the amino group is not alkylated.

Christensen, however, teaches (Page 3509, column 2, 1st full paragraph) that N-methylation of amino acids causes them to be preferentially transported by a different route than the non-alkylated compound allowing more control of the transport of the amino acid.

One of ordinary skill in the art would therefore have been motivated to alkylate the amino group of the compounds of Goodman to produce N-methyl compounds for

use in medical PET imaging which could be expected to show useful differences in distribution and rates of metabolic destruction. The corresponding ethylated compounds, as adjacent higher homologs of the methylated compounds, would be expected to show similar behavior and would therefore also be obvious. There would have been a reasonable expectation for success in view of Christensen's teaching that N-methylated compounds are taken up by Ehrlich cells.

Thus the instantly claimed compounds and method would have been obvious to one of ordinary skill in the art.

Conclusion

5. Claims 1-27 and 45-52 are pending. Claims 1-27, 45 and 47 are rejected. Claims 46 and 48-52 are held withdrawn from consideration.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul A. Zucker whose telephone number is 571-272-0650. The examiner can normally be reached on Monday-Friday 5:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Evonne Eyler can be reached on 571-272-0871. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1621

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Paul A. Zucker/
Primary Examiner, Art Unit 1621